UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 28, 2016

PC Code: 129121
DP Barcode: 432809

MEMORANDUM

Subject: **Fipronil**: Ecological Risk Assessment to Support the Section 18 Use of Fipronil-Treated Wheat Seed in the State of Washington

From: Michael Lowit, Ph.D., Ecologist
Stephen Wente, Ph.D., Biologist
Environmental Risk Branch I
Environmental Fate and Effects Division (7507P)

Michael Lowit 2016.04.28 17:12:02 -04'00'

STEPHEN WENTE Digitally signed by STEPHEN WENTE
DN: c=US, o=U.S. Government, ou=USEPA, ou=Staff, cn=STEPHEN WENTE, dnQualifier=0000034081
Date: 2016.04.28 17:21:54 -04'00'

Thru: Sujatha Sankula, Ph.D., Branch Chief
Gregory Orrick, Risk Assessment Process Leader
Environmental Risk Branch I
Environmental Fate and Effects Division (7507P)

for Sujatha, Greg Orrick 2016.04.28 17:25:06 -04'00'

Gregory Orrick 2016.04.28 17:24:17 -04'00'

To: Andrea Conrath, Risk Manager Reviewer
Tawanda Maignan, Product Manager, Team 9
Marion Johnson, Branch Chief
Risk Integration Minor Use, and Emergency Response Branch
Registration Division (7505P)

Timothy Ciarlo, Risk Manager
Bo Davis, Product Manager, Team 3
Marietta Echeverria, Branch Chief
Invertebrate-Vertebrate Branch 1
Registration Division (7505P)

The Environmental Fate and Effects Division (EFED) was asked to consider the potential risk from the Section 18 request to use fipronil-treated wheat seed (Fipronil 80DF TC) for control of wireworms in the state of Washington. This evaluation is based on the fipronil Registration Eligibility Decision (RED) chapter (USEPA, 2007) in part because the proposed application rate (0.0144 lb ai/A) is comparable to rates previously assessed in the RED for other fipronil-treated seed uses such as onion and corn (0.0178 to 0.11 lb ai/A) and the overall risk picture is expected to be substantially similar. A comprehensive assessment of all fipronil uses is currently scheduled to be conducted later in 2016 for Registration Review.

A potential risk concern is expected for direct effects to birds (acute and chronic; listed and non-listed species), mammals (acute and chronic; listed and non-listed species), aquatic invertebrates (acute and chronic; listed and non-listed species), and marine-estuarine fish (chronic; listed and non-listed species). The RED indicated that fipronil may present risk to terrestrial invertebrates; however, a quantitative analysis was not presented. In conclusion, consistent with other uses of fipronil there is a potential risk concern for aquatic organisms and terrestrial wildlife including listed species for the proposed use on wheat seed.

Additional Supporting Information

Birds and Mammals

There is a high degree of confidence that there is a potential risk concern for birds and mammals. Additional characterization was conducted on risk to birds and mammals to confirm the previous risk conclusions because the likelihood of a risk concern depends not only on the application rate but also on the characteristics of the seed. This characterization includes determining the foraged area of concern and foraged time of concern (birds only). In both cases these metrics represent the minimum foraging area or time required to obtain enough seeds (thereby active ingredient) to trigger a risk concern. As a cursory screen, the foraging area and time of concern were assessed for small birds and mammals (area only) to determine if the overall risk concerns for onion and corn seed uses are representative of the proposed wheat seed use. Indeed, the foraging area of concern is much smaller than the home range of 20 g birds (e.g., 2800-7000X smaller for a non-listed species) and 15 g mammals (e.g., 77-178X smaller for a listed species), indicating a plausible foraging area of concern for both birds and mammals. Notably, this conclusion is based on the best-case planting scenario where it is assumed that 99% of the seed is unavailable for foraging. Likewise, the necessary feeding time is plausible because the foraging time of concern (birds only) is very brief (e.g., 17-25 seconds for acute risk to 20 gram non-listed birds). Representative calculations are presented in **Appendix A**. Similar calculations can be made for chronic risk and other size classes; however, the cursory screen is sufficient for demonstrating that the onion and corn seed use assessment is representative of the proposed wheat seed use. Not only is there a potential concern if birds or mammals consume fipronil-treated seeds but it is anticipated that they will consume treated seeds because wildlife extensively use wheat for food year round (Martin et. al, 1951). Furthermore, a wide-range of wildlife may be exposed because numerous birds (e.g., many species of water birds, upland game birds, and song birds) and mammals (e.g., rabbits, squirrels, chipmunks, mice, and prairie dogs) are known to consume wheat seed. The known attraction of a wide range of animals to wheat seeds contributes significantly to the likelihood of a risk concern from the proposed use. In conclusion, the weight-of-evidence indicates a high degree of confidence that there is a potential acute and chronic risk concern for birds and mammals (listed and non-listed species) from the proposed wheat seed use.

Bees

There is a high degree of uncertainty in any potential risk concern for bees. Although the previous assessment on fipronil-treated seeds concluded that there was a potential risk concern for terrestrial invertebrates (USEPA, 2007), there was not a quantitative method at that time to assess risk to bees. A quantitative method was available for bees at the time of the most recent risk assessment (USEPA, 2014) but that assessment was for non-seed uses. Exposure from the

proposed seed use is expected to result primarily from translocation into plant tissues (pollen, nectar, exudates, and honeydew) or drift of abraded seed coat dust. Wheat is not known to be pollinator attractive and does not require insect pollination (USDA, 2015); therefore, any dietary exposure would be limited to pollinator-attractive, non-target blooming plants on or off the treatment field. Although bees could be exposed through direct contact with exposed seeds, this exposure pathway is much less likely and the proposed Tier I exposure methods do not include a methodology for addressing it. Likewise, EFED does not have a methodology for assessing soil uptake from pesticide released from seed nor exposure from abraded seed dust. Like seeds treated with other pesticides, it has been demonstrated that fipronil on treated seeds may be released with dust during the sowing process. For example, 1.37% of the fipronil on treated corn seeds was released during sowing in one study (Tapparo et al., 2012). It is important to consider however that numerous factors will impact the potential emission of fipronil-laden dust particles from seed applications and eventual exposure to bees (e.g., the seed, quality of the coating, the method of sowing, the size distribution of the emitted particulates, flight of bees near the sowing operation, distance of flowering plants from the sowing operation, etc.) (*see* review of dust emissions from treated seeds in Nuyttens et al., 2013). In conclusion, although there are potential exposure pathways for bees, there is a high degree of uncertainty in any potential risk concern due to a lack of standard methodology for estimating exposure at this time.

Aquatic Organisms

There is a high degree of confidence that there is a potential risk concern for aquatic organisms, particularly aquatic invertebrates, when planting depths are relatively shallow. It was assumed that the previously assessed use on onion seed (typical application rate of 0.048 lb ai/A, an incorporation depth of 0.635 cm, GA onion scenario; USEPA, 2007) is representative of risk concerns for the proposed use on wheat seed. The RED analysis assumed that all of the fipronil on the seed coat is available for degradation, runoff, and leaching.[1] Although there are differences between onion and wheat scenarios, estimated environmental concentrations (EEC) for the use on onion seed (0.048 lb ai/A) are likely higher than those for the proposed use on wheat seed (0.0144 lb ai/A) since the wheat seed treatment rate is approximately 1/3rd of the onion seed treatment rate. Nonetheless, risk concerns identified for onion seed would remain even if EECs for wheat seed are 1/3rd lower. There is some uncertainty about the impact of planting depth, a major determinant of aquatic exposure, on the EECs. The request letter accompanying the proposed Section 18 label indicates the "treated seeds will be planted at a typical depth of 1 to 2 inches following standard agronomic practices". However, no planting depth restriction appears on the proposed label. Treated seed planted at a depth less than 0.635 cm or 0.25 inch (the planting depth used in the RED onion seed treatment scenario) would likely result in greater aquatic exposure and risk. Conversely, a deeper planting depth (e.g., restricting planting depths to the minimum 1 inch planting depth indicated in the Section 18 request letter) may result in lower aquatic exposure and risk.

[1] Subsequent to the RED, the registrant provided short-term onion seed treatment wash-off data (MRID 47760001) to estimate 'available' fipronil *vs.* fipronil retained on the seed. EFED concluded that this data did not change the Agency's assumption that, over the long-term, 100% of the fipronil mass from the seed coat is available for degradation, runoff, and leaching since fipronil likely degrades slower in the environment than the seed coat potentially retaining the fipronil (USEPA, 2009).

Confidence in the aquatic risk concerns identified in the RED was increased by available monitoring data and the frequency of LOC exceedances over the modeled time series. Analysis of available water monitoring data showed that estimated acute exposure was consistent with monitored peak concentrations and that these monitored values would trigger acute concerns if substituted for model estimates in risk calculations. Although monitoring data were not specifically associated with pretreated seeds, some corresponded to in-furrow applications of fipronil to corn seed. The assessment also concluded that the risk concerns were not isolated to a short period of time given the many instances of daily (acute) and 21-day running average (chronic) EECs that triggered concerns for the typical application rate of onion seed. For example, there was an acute risk concern for non-listed freshwater invertebrate species on 9% of the days modeled in a 30-year time series. Likewise, daily exposure was high enough on 54% of the days modeled to trigger an acute risk concern for listed freshwater species and the 21-day running average exposure was high enough on 57% of the days modeled to trigger a chronic risk concern for freshwater species. The number of days triggering a concern for marine-estuarine invertebrates was even more than for freshwater invertebrates: 17% for acute risk to non-listed species, 60% for acute risk to listed species, and 66% for chronic risk.

Additional analyses of all toxicity data for aquatic invertebrates further suggested robustness of the identified risk concerns. The standard approach to assessing risk is to consider the most sensitive species within a taxonomic group; however, the RED also considered less sensitive endpoints for multiple species of aquatic invertebrates because acute toxicity data were available (one species had three endpoints). The analysis of the typical application rate for onion seed showed that there was an acute risk concern for listed freshwater invertebrate species based on 16 of 27 endpoints (8 of 27 for non-listed species) and for listed marine-estuarine invertebrate species based on three of four endpoints (two of four for non-listed species). This analysis indicated that uses triggering risk concerns with the most sensitive species endpoint would still trigger concerns if less sensitive organisms were considered instead.

In conclusion, the weight-of-evidence indicates a high degree of confidence in the risk concern for aquatic organisms, particularly aquatic invertebrates, when planting depths are relatively shallow; however, there is some degree of uncertainty without label restrictions on planting depth.

References

Martin, A.C., Zim, H.S., and Nelson, A.L., 1951. American Wildlife and Plants: A Guide to Wildlife Food Habits. Dover Publications, Inc., New York, 500p.

Nuyttens, D., Devarrewaere, W., Verbovenb, P., and Foque, D., 2013. Pesticide-laden Dust Emission and Drift from Treated Seeds during Seed Drilling: A Review. Pest Manag. Sci. 69:564-575.

Tapparo, A., Marton, D., Giorio, C., Zanella, A., Soldà, L., Marzaro, M., Vivan, L., Girolami, V., 2012. Assessment of the Environmental Exposure of Honeybees to Particulate Matter Containing Neonicotinoid Insecticides Coming from Corn Coated Seeds. Env. Sci. & Tech. 46:2592-2599.

USDA, 2015. Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen.

USEPA, 2007. Ecological Risk Assessment for Current and Proposed Residential and Crop Uses of Fipronil. Office of Chemical Safety and Pollution Prevention. U. S. Environmental Protection Agency. DP 331595+

USEPA, 2009. Review – The Movement of Fipronil from Treated Onion & Corn Seeds (MRID 47760001). Office of Chemical Safety and Pollution Prevention. U. S. Environmental Protection Agency. DP 365999

USEPA, 2011. Acres Planted per Day and Seeding Rates of Crops Grown in the United States. Office of Chemical Safety and Pollution Prevention. U. S. Environmental Protection Agency.

USEPA, 2014. FIFRA Section 18 Quarantine Exemption for the Use of Fipronil to Control the Tawny Crazy Ant in Louisiana. Office of Chemical Safety and Pollution Prevention. U. S. Environmental Protection Agency. DP 416110

USEPA, 2016. Refinements for Risk Assessment of Pesticide Treated Seeds – Interim Guidance. Office of Chemical Safety and Pollution Prevention. U. S. Environmental Protection Agency.

Appendix A: Representative Characterization of Risk to Birds and Mammals

Birds (Acute risk to a 20 gram non-listed bird)

Foraged Area of Concern

(1) Consumption of 12 seeds causes an acute risk concern for a 20 gram non-listed bird.

((0.02 kg bird * LD_{50} scaled for a 20g bird)/(mg ai/seed))*(LOC) = 11.9 seeds

- scaled LD_{50} = 8.14 mg/kg bw (calculated in T-Rex based on MRID 42918617)
- mg ai/seed = 0.0068
- LOC = 0.5

mg ai/seed = (maximum mg ai/lb seed)/(largest seed size for wheat)

- seeds/lb = 8,000 (range of 8,000-18,000 reported for wheat in USEPA, 2011)
- mg ai/lb seed = 54.5 (proposed label, converted from maximum 0.012 lb ai/100 lb seed)

(2) A foraging area of 0.0002-0.0005 ha is required to obtain 12 seeds based on the *least conservative* assumption regarding seed availability (1% of that applied). The foraging area is 2800-7000X smaller than the home range of a typical small bird (1.4 ha; USEPA, 2016). Some application methods for wheat may result in even greater seed availability and thus even smaller foraging areas.

(# seeds of concern)/(# seeds/A) = 0.0005-0.00125 A *or* 0.0002-0.0005 ha

- # seed of concern = 12 (*see* calculations above)
- # seeds/A = 9600-21,600

seeds/A = ((lb seed/A)*(seeds/lb))*(percentage of seed available for foraging)

- lb seed/A = 120 (proposed label, calculated from labeled maximum application rate of 0.0144 lb ai/A and labeled maximum ai concentration on seed of 0.012 lb ai/100 lb seed)
- seeds/lb = 8,000-18,000 (USEPA, 2011)
- percentage of seed available for foraging = 0.01 (i.e., 1%)

Foraged Time of Concern

(1) It will take approximately 17-25 seconds for a representative small bird (American Goldfinch) to consume enough seeds (12) to have a risk concern for a small, non-listed bird species. The American Goldfinch consumes seeds at least as large (reported in USEPA, 2016) as wheat seeds and resides throughout the US, including Washington State.

(# seeds of concern) * LN (X + (Y * seed weight)) = 17-25 seconds for American Goldfinch

- # seed of concern = 12 (*see* calculations above)
- X = 1.13 (species specific, USEPA, 2016)
- Y = 0.12 (species specific, USEPA, 2016)
- individual seed weight = 25-57 mg (based on 8,000-18,000 seeds/lb; USEPA, 2011)

Mammals (Acute risk to a 15 gram listed mammal)

Foraged Area of Concern

(1) Consumption of 47 seeds causes a risk concern for a 15 gram listed mammal.

((0.015 kg mammal * LD_{50} scaled for a 15g mammal)/(mg ai/seed))*(LOC) = 47 seeds

- scaled LD_{50} = 213.19 mg/kg bw (calculated in T-Rex based on MRID 42918628)
- mg ai/seed = 0.0068 (*see* calculations above for birds)
- LOC = 0.1

(2) A foraging area of 0.00084-0.00194 ha is required to obtain 47 seeds based on the *least conservative* assumption regarding seed availability (1% of that applied). The area is 77-178X smaller than the home range of a typical small mammal (0.15 ha; USEPA, 2016). Some application methods for wheat may result in even greater seed availability and thus even smaller foraging areas.

(# seeds of concern)/(# seeds/A) = 0.0021-0.0048 A *or* 0.00084-0.00194 ha

- # seed of concern = 47 (*see* calculations above for mammals)
- # seeds/A = 9600-21,600 (*see* calculations above for birds)